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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,196	06/19/2001	Richard S. Blumberg	G0694/7002 (JRV)	5225
23628	7590	04/07/2004	EXAMINER	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211			VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,196

Applicant(s)

BLUMBERG, RICHARD S.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18, 40-48 and 57-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 13, 14, 16-18, 40, 43, 44 and 46-48 is/are rejected.
- 7) ☒ Claim(s) 11, 12, 15, 41, 42, 45 and 57-62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/293,504, which claims the benefit of the filing date of provisional application 60/081,895.

Claims 1-9, 19-39 and 49-56 have been canceled previously.

Claims 57-62 were previously added.

Claims 10-18, 40-48 and 57-62 are currently pending.

1. In view of Applicant's remarks and the declaration under 37 CFR § 1.132 of inventor Richard Blumberg filed December 29, 2003, no outstanding grounds of rejection are maintained.

The following new ground of rejection necessitates that this Office Action be made NON-FINAL.

Applicant's arguments with respect to claims 10-18, 40-48 and 57-62 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10, 13, 14, 16-18, 40, 43, 44 and 46-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific suppression of isolated killer T cells using an antibody that increases cross-linking of biliary glycoprotein (CEACAM1) or a ligand comprising a biliary glycoprotein or fragment thereof, does not reasonably provide enablement for specific suppression of killer T cells using other agents or compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed invention is most broadly drawn to specific suppression of killer T cells under any conditions (claims 40-48 and 60-62) or in a subject (claims 10-18 and 57-59) by contacting the killer T cells with an agent that increases the cross-linking of biliary glycoprotein (CD66a). The instant specification demonstrates the suppression of killer T cell activity in propagated killer T cell lines or in isolated killer cells that have been enriched post-isolation via in vitro stimulation using CEACAM1

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specific monoclonal antibodies. The declaration under 37 CFR § 1.132 of inventor Richard Blumberg filed December 29, 2003 provides histological evidence that T cells could be suppressed in vivo using anti-CEACAM1 antibodies or with CEACAM1-based fusion proteins. However, while it is acknowledged that Applicant need not provide working examples for every embodiment of the claimed invention, the specification does not provide a reasonable expectation of success on the part of one skilled in the art to practice the claimed invention using agents other than the CEACAM1-specific antibodies or CEACAM1-based agents. The specification does not disclose other ligands or agents capable of cross-linking CEACAM1 and suppressing killer T cell function. Given the nature of the claimed invention, which is therapeutic intervention in a disease state, without additional guidance from the instant specification, the artisan would not be able to practice the claimed invention using agents beyond CEACAM1-specific antibodies or CEACAM1-based agents. It would require an undue amount of trial and error on the part of the practitioner to identify and select agents from the genus of agents as broadly as claimed. Therefore, it is not clear that the skilled artisan could predict the efficacy of agents not exemplified in the specification for specific suppression of killer T cells as encompassed by the claims.

In view of the breadth of the claims, the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

Conclusion

3. Claims 11, 12, 15, 41, 42, 45 and 57-62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *PV*
Patent Examiner
April 2, 2004

Pat J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
4/5/04